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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,032	03/30/2000	Samir Kumar Brahmachari	07064-01001	7985

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EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/539,032	BRAHMACHARI ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20041103*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/04 has been entered.

An action on the merits of pending claims 1-9 follows. All objections and rejections not reiterated below are hereby withdrawn.

Specification

The amendment filed 9/10/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a step of providing electronic data representing peptide libraries for selected organisms is new. The originally filed specification and original claim 1 recited a step of computationally generating overlapping peptide libraries for selected organisms. A step of computing and/or generating overlapping libraries is different from a step of merely providing a library. It is noted that as the originally filed sep recited actual computation/generation, the library of the original step would be expected to be different from that found in a pre-

existing database, thus neither the step nor the resulting library is supported by the originally filed disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Step (vii) of comparing proteins from pathogenic organisms with those of non-pathogens to select at least one conserved peptide not commonly conserved in both, and step (viii) of computationally validating conserved peptide sequences as potential drug target sequences, as recited in amended claim 1, are new. Applicant points to pages 5 and 7 of the specification for support for the newly added limitations of claim 1. Page 5 merely provides support finding a drug targeted against a specific peptide motif of a pathogenic organism, but does not teach comparison of conserved peptides in pathogens versus non-pathogens, nor for computational validation of a peptide as a drug target. Page 7 provides support for comparison of genomes, as argued by

applicant, but does not provide support for a step of comparison of conserved peptides in pathogens versus non-pathogens anywhere. In fact, page 6 of the originally filed specification clearly teaches that an object of the inventive method is to find peptides "that are invariant across all the pathogenic and nonpathogenic bacterial genome." Examples 2, 5 and 6 on pages 14-15 of the originally filed specification describe a method of identifying peptide seqeunces which are invariant in all of the organisms selected, which include both pathogenic and nonpathogenic species.

Example 7 on page 16 of the specification discloses DNA gyrase as protein which is absent in humans and has been considered as a drug target, and further discloses sequences which are invariant across various bacterial species, but does not disclose either searching for one of the conserved peptides in the host organism nor "computationally validating" any conserved sequences.

For the reasons set forth above, the claims are rejected for reciting new matter.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. A step of computationally validating a conserved peptide sequence as a drug target, as recited in amended step (viii) of claim 1, is not enabled. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC

1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The specification provides no support for the newly recited step of claim 1, as set forth above. The instant specification does not describe any computational step of predicting, validating, etc. as peptide as a drug target. Mere comparison of sequences is not generally considered by those in the art to be a computational step.

Methods of pattern recognition for distinguishing one species from another by sequence comparison are known in the art (PLIKAYTIS et al. (J. General Microbiol. (1992) vol. 138, pp. 2265-2273), however, these methods require generation of a probability matrix using a plurality of sequences known to be different between the species in question. Methods of comparing and calculating similarity or differences between nucleic acids and proteins are also well known (see e.g. Wilbur et al. PNAS (1983) vol. 80, pp. 726-730); however, a known algorithm is used and Wilbur teaches that the results vary depending on the parameters chosen (p. 729). Neither the claims nor the instant specification recite or teach any particular algorithm, matrix, etc. for performing a "computational validation," nor are any parameters set forth for determining what is or is not considered "different" when comparing peptides between bacteria and a host; i.e. in order to "validate" a potential drug target. The level of skill in the art is acknowledged to be high. Despite this, and due to the lack of teaching for any computational analysis or comparison of peptide sequence in a host versus any (single or multiple) bacterial species, one skilled in the art would have to "guess" at what kind of computation to perform, what parameters are necessary, and how to determine whether

a peptide sequence is "validated" as a potential drug target. This constitutes undue experimentation. For these reasons, the claims are not enabled.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "[invariant]" is recited in line 2. Use of the brackets renders it unclear whether applicant intends the term in the brackets to be positive limitation of the claim. It is further unclear whether applicant actually intends an "invariant conserved peptide," or is attempting to delete the term "invariant." It is noted that all other deletions to the claims are noted in the amendment by a strike-through line.

Conclusion

Claims 1-9 are rejected; the specification is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
11/23/04